4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0610]

Increasing the Quality and Efficiency of Clinical Trials

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of the efforts of the Center for Drug Evaluation and Research/ Office of Medical Policy to increase the quality and efficiency of clinical trials. The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of Medical Policy is announcing its intent to accept and consider a single-source application for the award of a grant to the Duke University's Duke Translational Medicine Institute (DTMI).

DATES: The application due date is June 30, 2014, by 11:59 p.m. Eastern Time. The expiration date is July 1, 2014.

ADDRESSES: Submit electronic applications to: http://www.grants.gov. For more information, see section III of the SUPPLEMENTARY INFORMATION section of this notice.

FOR FURTHER INFORMATION CONTACT: Mark Lauda, Office of Medical Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10990 New Hampshire Ave., Bldg. 51, rm. 2212, Silver Spring, MD 20993, 301-796-0381, email: Mark.Lauda@fda.hhs.gov; or Lisa Ko, Office of Acquisition & Grants Services, Food and Drug Administration, 5630 Fishers Lane, Rockville, MD, 240-402-7592, email: Lisa.Ko@fda.hhs.gov.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at http://www.grants.gov. Search by Funding Opportunity Number: RFA-FD-14-017.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA-FD-14-017

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A. Background

It has long been recognized that the clinical trial enterprise will need to evolve in order to meet the demand to provide data to support evidence-based decisionmaking. A memorandum of understanding (MOU) between FDA and Duke University published in the Federal Register on November 23, 2007, served as the basis for the establishment of the Clinical Trials Transformation Initiative (CTTI). CTTI is a public-private partnership whose mission is to identify and promote practices that will increase the quality and efficiency of clinical trials. This award will be made to DTMI within Duke University to identify and implement projects and disseminate resulting findings that will increase the quality and efficiency of clinical trials, CTTI's mission.

CTTI membership is broad and includes stakeholders from government, industry, patient advocacy and consumer groups, professional societies, clinical research organizations, and academia. CTTI helps to effect change through the conduct of projects that identify existing inefficiencies, elucidate superior practices, and/or provide innovative approaches to evidence generation and medical product development. CTTI conducts projects that are either: (1) proposed by its member organizations, including FDA, developed during review by its

Steering Committee, and endorsed by its Executive Committee or (2) responsive to urgent needs of FDA.

The opportunity for meaningful interaction with a broad set of stakeholders committed to improving the clinical trial enterprise and also the ability to rapidly gather data to address emerging issues offer significant value to the clinical trial enterprise. Since its inception, CTTI has undertaken many projects that have direct relevance to FDA's mission, including investigational new drug (IND) safety reporting, clinical trial monitoring, use of central investigational review boards, and antibacterial drug development.

B. Research Objectives

The goals of this program are to develop and maintain an administrative and scientific infrastructure to support the creation and execution of a series of projects under the auspices of CTTI that will increase the quality and efficiency of clinical trials. The following are examples of activities that could be supported by this grant:

- Maintaining an adequate administrative and scientific infrastructure to implement all related projects under this collaborative effort.
- Identifying and/or hiring a sufficient number of qualified personnel to conduct activities, including project management, such as review of project milestones for degree of completion, preparation/reporting of project findings, periodic and final reports, and for subsequent distribution in the public domain.
- Developing plans for the conduct of identified projects.
- Identifying, securing, and/or building, and effectively leveraging other resources for the conduct of identified projects.

- Upon completion of a given project, generating project results and recommendations and proposing related studies/projects, if needed, to build on the findings of the project and continuing to leverage established resources and personnel.

C. Eligibility Information

The following organization is eligible to apply: DTMI located within Duke University.

II. Award Information/Funds Available

A. Award Amount

This is a multiyear grant. FDA/CDER intends to fund up to $7,500,000 in total costs (direct and indirect) in Fiscal Year 2014. Awards are contingent upon the availability of funds.

Subject to the availability of Federal funds and successful performance of the FOA's stated goals and objectives, four additional years of support may be available. Funding beyond the first year will be noncompetitive and will depend on: (1) satisfactory performance during the preceding year and (2) the availability of Federal fiscal year funds.

Application budgets need to reflect the actual needs of the proposed project and should not exceed the following in total costs (direct and indirect):

Year 01: $7,500,000

Year 02: $7,500,000

Year 03: $7,500,000

Year 04: $7,500,000

Year 05: $7,500,000

B. Length of Support

The scope of the proposed project should determine the project period. The maximum project period is 5 years.

III. Electronic Application, Registration, and Submission

Only electronic applications will be accepted. To submit an electronic application in response to this FOA, applicants should first review the full announcement located at http://www.grants.gov. Search by Funding Opportunity Number: RFA-FD-14-017. (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.) For all electronically submitted applications, the following steps are required.

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number
- Step 2: Register With System for Award Management (SAM)
- Step 3: Obtain Username & Password
- Step 4: Authorized Organization Representative (AOR) Authorization
- Step 5: Track AOR Status
- Step 6: Register With Electronic Research Administration (eRA) Commons

Steps 1 through 5, in detail, can be found at http://www07.grants.gov/applicants/organization_registration.jsp. Step 6, in detail, can be found at https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp. After you have followed these steps, submit electronic applications to: http://www.grants.gov.

Dated: May 15, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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